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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/555,704	06/02/2000	Toyokazu Ishikawa	9150-0008.10	9123

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EXAMINER

BROWN, STACY D

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 11/27/2001

12

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Applicati n No.

09/555,704

Applicant(s)

ISHIKAWA ET AL.

Examiner

Stacy S Brown

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 02 June 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 9-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 9-16 is/are rejected.
- 7) ☒ Claim(s) 5 and 13 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 June 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### **DETAILED ACTION**

1. The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to **Group Art Unit 1648**.
2. Applicant's preliminary amendments are acknowledged and entered. Claim 8 has been cancelled, and new claims 11-16 have been added. Claims 1-7 and 9-16 are pending and examined.

#### ***Claim Objections***

3. Claims 5 and 13 are objected to because of the following informalities: the temperature range for inactivation is cited to be in a range of about 40-100 degrees Celsius. It is the examiner's understanding from the specification on page 11, that Applicant meant 4-10 degrees Celsius. Appropriate correction is required.

#### ***Specification***

4. Applicant is reminded of the proper content of an abstract of the disclosure.

Abstract of the Disclosure: A brief narrative of the disclosure as a whole in a single paragraph of 150 words or less on a separate sheet following the claims.

#### ***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 9 and 11-16 are rejected under 35 U.S.C. 102(a) as being anticipated by  
Huiying et al. (Virologica Sinica, Vol. 13, No. 3, Sept. 1998) or Takegami et al. (Antiviral  
Research, Vol. 37, 1998). The claims are drawn to an inactivated virus particle and method for  
producing said particle. The particle is a reinforced immunogen prepared from a culture of cells  
infected with a virus belonging to a group of Japanese encephalitis viruses (JEV), wherein a  
neutralizing antibody titer of the anti-serum obtained by immunization with the particles is 2-10  
times greater than the antibody titer obtained by immunization with inactivated virus particles  
prepared from virus cultured in mouse brain. The preferred cell line is Vero. The method  
comprises inactivation of the particles at about 40-100 degrees Celsius, and purification is  
accomplished by physical means (as opposed to chemical means). The strain of virus can be a  
Beijing strain or a ThCMAR67/93 strain of JEV. Also claimed is an inactivated vaccine and  
diagnostic agent comprising the inactivated virus particles described above. The instant  
specification on page 4 discloses that novel JEV particles are provided having outstanding  
immunogenicity or antigenicity as an inactivated vaccine, however, "the scientific basis for this  
is unknown." **Huiying et al.** (*Virologica Sinica*, Vol. 13, No. 3, Sept. 1998) teach large-scale  
purification of inactivated Japanese encephalitis vaccine from Vero cells by zonal centrifugation,  
see abstract. **Takegami et al.** disclose Vero cells infected with JEV that were inactivated and  
purified, see abstract and page 38, column 2, section 2.3. Although Huiying et al. (*Virologica*  
*Sinica*, Vol. 13, No. 3, Sept. 1998) or Takegami et al. do not disclose the comparative antibody  
titers between their immunogens and those grown in mouse brain, it is an inherent property  
because the claimed invention and the prior art produced the particles using the same methods.

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The inactivated virus particle and the method for producing said particle are known in the art, and any property associated with the known particle and method of producing are inherent.

Claims 1-7, 9 and 11-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Huiying et al. (Virologica Sinica, Vol. 10, No. 4, 1995). The claims are described above.

Huiying et al. (Virologica Sinica, Vol. 10, No. 4, 1995) disclose JEV adapted in Vero cells and inactivated particles, see abstract and table 3. The instant specification on page 4 discloses that novel JEV particles are provided having outstanding immunogenicity or antigenicity as an inactivated vaccine, however, "the scientific basis for this is unknown." Although Huiying et al. (Virologica Sinica, Vol. 10, No. 4, 1995) does not disclose the comparative antibody titers between their immunogens and those grown in mouse brain, it is an inherent property because the claimed invention and the prior art produced the particles using the same method. The inactivated virus particle and the method for producing said particle are known in the art, and any property associated with the known particle and method of producing are inherent.

### ***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

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evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7 and 9-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huiying *et al.* (Virologica Sinica, Vol. 13, No. 3, Sept. 1998) or Takegami *et al.* (Antiviral Research, Vol. 37, 1998) or Huiying *et al.* (Virologica Sinica, Vol. 10, No. 4, 1995) in view of Kotaro *et al.* (Japanese Patent Abstract, 07265093). The teachings of both of Huiying *et al.* and Takegami *et al.* are summarized above. Huiying *et al.* and Takegami *et al.* do not teach a diagnostic kit as claimed in claim 10, however, Kotaro *et al.* disclose production of antigens from JEV using mammalian cells that are used for medication or diagnostics, see abstract. It would have been obvious to use the inactivated immunogens of both of Huiying *et al.* and Takegami *et al.* in a diagnostic kit. One would have been motivated by Kotaro *et al.* to use the known immunogens in a diagnostic kit because it is well-known and practiced in the art to use purified immunogens in diagnostic kits as well as in vaccines (medications), as evidenced by Kotaro *et al.* One would have had a reasonable expectation of success that the immunogens of Huiying *et al.* and Takegami *et al.* would have been useful in a diagnostic kit because the inactivated immunogens elicit antibodies in the subject, and would therefore elicit antibodies in an assay. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

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***Conclusion***

7. No claim is allowed.

Papers relating to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 located in Crystal Mall 1. The Fax number for Art Unit 1648 is (703) 308-4426. All Group 1600 Fax machines will be available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Stacy S. Brown, whose telephone number is (703) 308-2361. The Examiner can normally be reached on Monday through Friday and alternate Wednesdays from 6:30 AM-4:00 PM, (EST). If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, James C. Housel, can be reached at (703) 308-4027. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Stacy S. Brown  
November 19, 2001



HANKYEL T. PARK, PH.D  
PRIMARY EXAMINER